

## International BfR Symposium: Experts discuss continuing international harmonisation of terminology in developmental toxicology

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The toxicological assessment of pesticides, biocides and chemicals comprises, amongst others, the potential detrimental effects on reproduction and development in humans and animals.

An objective and transparent scientific evaluation of anomalies observed in offspring in experimental animal studies is indispensable for the assessment.

The Federal Institute for Risk Assessment (BfR) organised an International Symposium on developmental toxicology that took place from 14 to 16 May 2014. The aim of the symposium was the continuing international harmonisation of the terminology used in the assessment of embryo- / fetotoxic findings and thus to improve the health risk assessment of pesticides, biocides and chemicals. Among the more than 70 participants were experts from a total of 14 countries, including representatives of the teratology societies from Japan, the USA and Europe.

Evaluation of embryo- and fetotoxicity is an essential part of developmental toxicology and hence indispensable for the assessment of the potentially harmful effects of chemical substances in humans and animals. Developmental toxicity manifests itself, for example, in structural damage or even death in utero. The legally required experimental studies categorise structural damage as external, visceral, and skeletal anomalies in the fetus. For an objective and transparent scientific assessment of anomalies within the framework of the health risk assessment of pesticides, biocides and chemicals, international harmonisation of the terminology used to describe findings is indispensable.

The DevTox Project was founded in 1995 and is concerned with the harmonisation of the terminology used in the field of developmental toxicology ([www.devtox.org](http://www.devtox.org)). For this purpose standardised terminology, visualisation of anomalies, and a database for laboratory findings in developmental toxicity studies have been established over the course of seven international workshops held in Berlin. The DevTox project is a joint project of the BfR, the Fraunhofer ITEM and the Charité Institute for Clinical Pharmacology and Toxicology. The main aim of the 8<sup>th</sup> Berlin workshop and the Symposium on development toxicology was to reach agreement on classification of new terminology as well as integration of this new terminology into the internet-based database of anomaly images.

Therefore, one important point of the discussion was the classification of external, skeletal and visceral findings (and corresponding images) into malformations, variations and non-classifiable anomalies (grey zone anomalies). Furthermore, the experts discussed how comparative aspects of reproductive toxicology (i.e. relationship between development anomalies in humans and laboratory animals as well as between prenatal effects and postnatal consequences) can be integrated into the “DevTox Project”.

From the perspective of the BfR, the symposium has produced the following main outcomes:

- The development of a project for the comparative assessment of developmental anomalies in humans and laboratory animals seems very important for the regulatory

assessment of pesticides, biocides and chemicals and also for the university-based training of physicians and toxicologists.

- New methodological approaches for non-animal alternative testing methods should be developed within the framework of a strategy for risk assessment of developmental anomalies in the 21<sup>st</sup> century.
- An additional assessment of developmental toxicity data of the active substance glyphosate taking into account epidemiological data has confirmed that glyphosate is not to be classified as harmful for development.

A workshop report and the presentation of the symposium will be published soon at [www.devtox.org](http://www.devtox.org).